What You Should Know About Clinical Trials

Clinical trials are carefully controlled and scientifically monitored studies on drugs, procedures, or other interventions that must take place in patients after they are granted government approval.

How do clinical trials work?

The Process

1. **Screening**: The process begins with comprehensive testing to determine eligibility for participation in a specific trial.
   - **Overall health assessment**: Evaluates general health status.
   - **Family history and prior treatments**: Ensures patients meet specific criteria.
   - **Cancer type**: Identifies the type of cancer.
   - **Age**: Determines eligibility based on age.
   - **Prior treatments**: Evaluates the effectiveness of previous treatments.
   - **Family history**: Considers genetic factors.
   - **Cancer type**: Identifies specific types of cancer.

2. **Protecting patients**: The Institutional Review Board (IRB) ensures that clinical trials are conducted ethically and safely.
   - **Monitors the progress of the trial**: Ensures participant safety.
   - **Independent committee**: Oversees the trial to ensure it is safe and ethical.

3. **Participant benefits**: Patients enrolled in clinical trials may benefit from:
   - **New treatments**: Access to experimental therapies.
   - **Side effect monitoring**: Regular checks for side effects.
   - **Care from clinical trials**: Access to expert care.

4. **Risks of participating**: Patients may face:
   - **Unexpected side effects**: Potential for severe reactions.
   - **Reduced access to care**: Limited treatment options.
   - **Economic impact**: Increased medical costs.

The GOAL

1. **Patient goals**: The goal is to improve treatment outcomes.
   - **Measure how severe they are**: Evaluates treatment effectiveness.
   - **Identify side effects**: Monitors for adverse reactions.

2. **Clinical research**: The research process includes:
   - **Safe maximum dose**: Determines the maximum tolerated dose.
   - **Understanding the disease**: Identifies drug targets.
   - **Predicting the outcome**: Uses biomarkers to predict response.

Who qualifies for clinical trials?

Patient populations are selected for clinical trials and may receive treatments that are not approved by the Food and Drug Administration (FDA). These trials are typically randomized to ensure patient safety.

Who looks out for the patient?

A clinical trial is led by a research team of nurses, doctors, lawyers, and other professionals. The Institutional Review Board (IRB) oversees the trial to ensure it is safe and transparent.

What are the benefits and risks?

Participating in a clinical trial can help patients:

- **Free or low-cost drugs**: Access to experimental treatments.
- **Side effect monitoring**: Regular checks for adverse reactions.
- **Care from clinical trials**: Access to expert care.

Risks of participating in a clinical trial may include:

- **Unexpected side effects**: Potential for severe reactions.
- **Reduced access to care**: Limited treatment options.
- **Economic impact**: Increased medical costs.

Clinical trials by the numbers

- **8 years**: Time from when a drug is discovered to when it is approved for use.
- **55 cancer drugs**: Number of drugs approved after extensive clinical trials.
- **10 Phase I trial**: The smallest number of patients in a clinical trial.